The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

#### UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte D. WADE WALKE, NATHANIEL L. WILGANOWSKI, GREGORY DONOHO and C. ALEXANDER TURNER JR.

Appeal No. 2004-2302 Application No. 09/755,016 MAILED

**JAN 0 6** 2005

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

ORDER UNDER 37 CFR § 41.50(d)

Before WILLIAM F. SMITH, ADAMS and GRIMES, <u>Administrative Patent Judges</u>. GRIMES, Administrative Patent Judge.

### ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d),<sup>1</sup> we require Appellants to address the following matters:

We invite attention to commonly assigned Application No. 09/714,882.<sup>2</sup> That application was the subject of an appeal to this board (Appeal No. 2004-1732), which was decided on September 24, 2004.

<sup>&</sup>lt;sup>1</sup> "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

The issues and arguments in Appeal No. 2004-1732 bear close resemblance to those in this appeal. In Appeal No. 2004-1732, the broadest independent claim (claim 2) was directed to "[a]n isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:2." The polypeptide of SEQ ID NO:2 was disclosed to have sequence similarity to Notch receptor ligands, but the specification did not disclose the biological function of the putative ligand. The only issue in Appeal No. 2004-1732 was whether the specification disclosed a patentable utility for the claimed invention.

In Appeal No. 2004-1732, the appellants argued, among other things, that the claimed nucleic acids had utility because they could be used in methods that do not depend on the biological activity of the encoded protein. The appellants argued that the claimed nucleic acids were useful "in determining the genomic structure of the corresponding human chromosome . . ., for example mapping the protein encoding regions" and that they "are useful for functionally defining exon splice-junctions."

Application No. 09/714,882, Board decision mailed 9/24/04, page 18.

The appellants in Appeal No. 2004-1732 also argued that the claimed nucleic acids could be used in "gene chips" or "DNA chips" to monitor gene expression. The appellants argued that "[s]uch "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that <u>enhance</u> the utility of

<sup>&</sup>lt;sup>2</sup> The named inventors in the instant application are D. Wade Walke, Nathaniel L. Wilganowski, Gregory Donoho and C. Alexander Turner Jr. In Application No. 09/714,882, the inventors are C. Alexander Turner Jr., Michael C. Nehls, Glenn Friedrich, Brian Zambrowicz, and Arthur T. Sands.

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such DNA gene chips, such as the presently claimed sequences encoding a testis specific Notch ligand, must in themselves be useful." Id.

Finally, the appellants argued that Appellants the claimed polynucleotides were useful because of a disclosed polymorphic position in SEQ ID NO:1: "the skilled artisan would readily recognize and easily believe that the presently described polymorphic markers [sic] could be useful in forensic analysis. The fact that forensic biologists use polymorphic markers such as those described by Appellants every day provides more tha[n] ample support for the assertion that forensic biologists would also be able to use the specific polymorphic markers [sic] described by Appellants in the same fashion." ld., page 16.

The panel that decided Appeal No. 2004-1732 reviewed governing principles of law; addressed and rejected the appellants' arguments premised on DNA chips, gene mapping, and exon splice junctions; and concluded that "Appellants' disclosure in th[at] case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Id., page 27. Accordingly, the examiner's decision, rejecting all of the pending claims in Application No. 09/714,882, was affirmed.

Like the claims in Application No. 09/714,882, in this appeal the broadest independent claim (claim 2) is directed to a nucleic acid comprising a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:4 and hybridizes to SEQ ID NO:3 under specified conditions. The specification discloses that SEQ ID NO:4 "share[s] structural similarity with animal proteases, and particularly trypsin-like serine proteases." See page 2. All of the claims on appeal stand rejected on the basis that

the specification does not disclose a patentable utility for the claimed invention.

Examiner's Answer, page 3.

The Appeal Brief in this appeal includes essentially the same arguments that were made and rejected by the previous merits panel in Appeal No. 2004-1732. For example, Appellants argue that:

- "Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of human chromosome 12 that contains the gene encoding the given polynucleotide. . . . The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome." (Appeal Brief, page 15);
- "[T]he described sequences are useful for functionally defining exon splice-junctions." (<u>id.</u>, page 14);
- "[T]he present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips. . . . Such 'DNA chips' clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that <u>enhance</u> the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful." (<u>id.</u>, page 12);
- "[A]II that is required to support Appellants' assertion of utility is for the skilled artisan to believe that the presently described polymorphic markers could be useful in forensic analysis. The fact that forensic biologists use polymorphic markers such as those described by Appellants every day provides more than ample support for the assertion that forensic biologists would also be able to use the specific polymorphic marker described by Appellants in the same fashion." (id., page 8).

On these facts, we require Appellants to explain why we should again address the same line of argument in this case: since the same arguments were considered and thoroughly addressed in Appeal No. 2004-1732, why would the previous panel's treatment of those arguments not be dispositive here? In particular, why should the facts and arguments set forth in the briefing of this appeal lead to a different conclusion

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than that reached by the panel in Appeal No. 2004-1732, which rejected the same arguments? We note that, according to PTO records, the appellants in Appeal No. 2004-1732 (Application No. 09/714,882) did not request rehearing under 37 CFR § 41.52, nor did they appeal the Board's decision, within two months from the date of the Board decision.

#### Conclusion

In conclusion, we require Appellants to address the foregoing matters "consider[ed] to be of assistance in reaching a reasoned decision on the pending appeal." 37 CFR § 41.50(d). We caution, however, that this is not an invitation to expand on points raised in the Appellants' brief or to rehash arguments already set forth in the brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2004-1732. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellants' response should be confined to the matters outlined above.

## Time Period For Response

A period of one month from the date of this order is set for Appellants' response.

This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

William F. Smith

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

) BOARD OF PATENT

APPEALS AND

INTERFERENCES

Eric Grimes

Administrative Patent Judge

Application No. 09/755,016

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